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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/523,273 | 01/31/2005 | Dennis M Klinman | 4239-66339-03 | 2295 |
| 36218 | 7590 | 09/21/2007 | EXAMINER | |
| KLARQUIST SPARKMAN, LLP | | | HORNING, MICHELLE S | |
| 121 S.W. SALMON STREET | | | ART UNIT | |
| SUITE #1600 | | | PAPER NUMBER | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/523,273 | Applicant(s) KLINMAN ET AL. | |
| | Examiner Michelle Horning | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-27, 29, 30, 32-34, 37-43, 51 and 52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-27, 29-30, 32-34, 37-43 and 51-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/16/2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This office action is responsive to communication filed 8/2/2007. The status of the claims is as follows: claims 24-27, 29-30, 32-34, 37-43 and 51-52 are under current examination. Applicant elected species SEQ ID NO: 2. This sequence is not found free of the prior art (see WO9323572-A1, 1993 as a single example). No other sequences were searched, given no generic claim was found to be allowable. The elected method is free of the prior art.

Applicant's election with traverse of Group II in the reply filed on 8/2/2007 is acknowledged. The traversal is on the ground(s) that are not clearly stated. This is not found persuasive because there is no argument to consider by the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

The drawings filed 3/16/2004 are accepted by the Examiner.

Objections to the Specification

The use of the trademarks has been noted in this application, see multiple examples throughout specification, including pages 30-31. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-27, 29-30, 32-34, 37-39, 43 and 51-52 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-25, 27 and 68-75 of copending Application No. 10/489, 839. While both sets of claims are not identical, both are drawn to a method of treating a subject with inflammatory arthropathy comprising the same steps, products and limitations.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-27, 29-30, 32-34, 37-43 and 51-52 are rejected under 35 U.S.C.

112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Enablement is considered in view of the *Wands* factors.

Nature of the invention. The claims are drawn to a method of treating inflammatory arthropathy in a subject by administering a G-tetrad forming ODN, comprising 2-20 TTAGGG motifs and has a CD value greater than 2.9.

Breadth of the claims. The claims are broad, encompassing all inflammatory joint diseases and all ODN structure meeting the limitations defined in claim 24.

State of the art. The art teaches that LPS and CpGs both induce arthritis and both have served. See Matsukawa et al (1993) and Deng and Tarkowski (2000).

Guidance in the specification. The specification fails to persuasively correlate the successful treatment of inflammatory arthropathy by the suppressive ODNs of the claimed methods and the suppression of CpG-induced inflammation at the

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ligand/receptor level. While CpGs are known in the prior art to induce inflammations, such as arthritis, post filed art by the Inventors disclose that such ODNs suppress the immune system by interfering with the maturation of endosomal vesicles and the co-localization of CpG ODN with TLR9 in these vesicles. *Thus, this is a ligand-receptor interaction occurring in the very early events in CpG-mediated signaling* (Gursel et al, 2003, page 1399). Given this information, it is not clear to the Examiner how the state of inflammatory arthropathy has been successfully achieved for treatment if the suppression occurs in the very early events in CpG-mediated signaling. Examination of the method steps used in the specification revealed that in some experiments suppressive ODNs were injected prior to the CpGs (see pages 38-9) and in others, CpG ODNs were co-injected with the suppressive ODNs (page 35). This would suggest to the ordinary artisan that the suppressive ODNs may affect the CpG-mediated signaling at the level of the ligand-receptor before the state of inflammatory arthropathy is achieved.

As noted above, LPS is also taught in the art to induce arthritis. The instant specification states the following: "In parallel studies, suppressive ODN prevented the arthritis induced by bacterial DNA but not LPS (data not shown)" (paragraph 249). Thus, the ordinary artisan would hypothesize that the effect of suppressive ODN is specific to the CpG ODNs, and not to the state of inflammatory arthropathy itself.

The specification discloses a method of attenuating CpG-mediated immune responses by administration of the disclosed ODNs, but not for the successful treatment of inflammatory arthropathy. It is also noted that attenuation of CpG-mediated immune

responses by suppressive ODNs is known in the prior art and Gursel et al (discussed above) provides a mini-review of other references in this paper's Discussion. Also noted for reasons of record are the striking similarities of the drawings between those of the Gursel et al reference and those of the instant specification. While the data may be similar in both, the conclusions are incongruent.

Working Examples. Example of CpG-mediated immune responses and their suppression by the ODNs of the claimed methods are provided. No example demonstrates the state of inflammatory arthropathy in the subjects. Applicant is invited to show otherwise.

Predictability in the art. There is no way one could predict this method in any aspect, given the lack of crucial support in the specification.

Amount of experimentation necessary. Much experimentation is required, including a proper model for the successful treatment of inflammatory arthropathy and determining the structure of all ODNs meeting the given limitations that are functionally suppressive.

For the reasons discussed above, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed methods.

Conclusion

NO claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michelle Horning
Patent Examiner

/Bruce Campell/
Supervisory Patent Examiner
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